MAQUET Cardiopulmonary AG

Premarket Notification Special 510(k) - Change due to recall/corrective action
Modified QUADROX-iR Oxygenators

510 (k) Summary
[As required by 21 CFR 807.92(c)]

Date: October 22, 2013

Submitter:
MAQUET Cardiopulmonary AG
Kehler Straße 31
76437 Rastatt
Germany

NOV 1 2 2013

Contact Person:
Whitney Törning
Director of Regulatory
MAQUET Cardiovascular
45 Barbour Pond Drive
Wayne, NJ 07470
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Device Trade Names: QUADROX-iR Adult / Small Adult

Common/Usual name: Oxygenator with integrated centrifugal pump and with / without integrated Arterial Filter

Classification Name: Oxygenator, cardiopulmonary bypass, heat exchanger, cardiopulmonary bypass, filter, blood cardiopulmonary bypass, arterial line, non-roller type blood pump, cardiopulmonary bypass

Device Modification

The only modification consists of adding a reusable stainless steel holding clamp as an interim protective safeguard / corrective action to prevent the inlet and/or outlet connector from disconnection. The holding clamp is applied by the perfusionist prior to use.

Legally marketed MAQUET Predicate Devices:

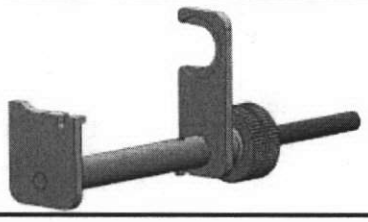
Primary predicate device: QUADROX-iR Adult K102726, QUADROX-iR Small Adult K102726

Secondary predicate devices: QUADROX-i Adult Microporous Membrane Oxygenators K132829, QUADROX-i Small Adult Microporous Membrane Oxygenators K132829, QUADROX-i Pediatric Microporous Membrane Oxygenator K132829, QUADROX-i Neonatal Microporous Membrane Oxygenator K132829, QUADROX-iD Adult Diffusion Membrane Oxygenator K132829 and QUADROX-iD Pediatric Diffusion Membrane Oxygenator K132829.

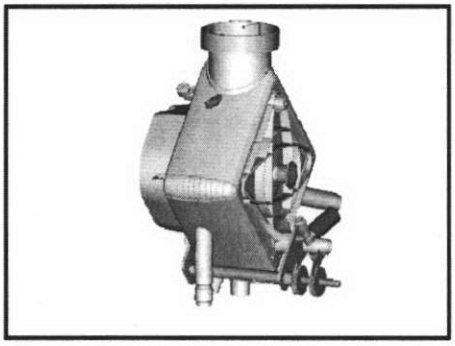
Device Description:

Holding Clamp – interim protective safeguard and component of the QUADROX-iR Oxygenator

The holding clamp is applicable to all QUADROX-iR oxygenators which are subject to this submission. The following table provides an overview of the QUADROX-iR oxygenator models and the suitable holding clamp.

Catalogue number	Holding clamp - picture	suitable for*
HKH 3572		HMO 70100 USA - Quadrox iR Adult w/o filter HMO 71100 USA- Quadrox iR Adult with filter HMO 50100 USA - Quadrox iR Small Adult w/o filter HMO 51100 USA - Quadrox iR Small Adult with filter

* The above listed QUADROX-iR Oxygenator models may also be provided with BIOLINE Coating and may be sold in combination with other devices as described in the original 510(k) (K102726).



Picture: QUADROX-iR with Holding Clamp

QUADROX-iR (disposable) as part of the CARDIOHELP System, the indications for use is as follows:

The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support during procedures requiring cardiopulmonary bypass (for periods up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport[1].

The CARDIOHELP System in configuration with the QUADROX-iR is intended to be used in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery (for periods for up to six hours).

[1] (Note: This section of the indications for use statement does not refer to the HLS/HIT Set Advanced (K102726) and therefore it is not subject to this Special 510(k)).

Technological Characteristics:

The modified device as mentioned above is identical to the originally cleared device, with the exception that an added reusable stainless steel holding clamp is applied by the perfusionist prior to use as an interim protective safeguard in the unlikely event that the inlet and/or outlet connector would become loose. Besides this difference, the proposed device is the same in design, intended use, method of operation, components, packaging, and fundamental scientific technology as the predicate device (QUADROX-iR Adult and Small Adult).

Non-clinical Tests:

The modified device was subjected to **design verification** tests which are based on the risk assessment. The tests are designed to show that the clamp can be mounted on the Oxygenator, so that the clamp will stay in place during its use, and in the unlikely event that the bonding of the connectors to the housing would fail the connector would not detach from the housing..The tests simulate relevant mechanical conditions in the use of the Oxygenators. The following mechanical tests were performed:

- **Holding Forces –** Force applied to the connectors to hold the clamp in place
- **Pull off Forces** – Force to remove the holding clamp from the housing perpendicular to the clamping force.
- **Vibration Test with Shaker —** Simulate impact forces up to 3G and confirm the secure attachment of the clamp under repeated impact.
- **Vibration Test with Cardiohelp** – Test to demonstrate that the clamp stays securely fixed over the total application time of up to 6 hours.
- **Usability test** – This test was performed in three hospitals and evaluated as to whether the clamp could be mounted using the Instruction for Use.

The holding clamp as an external component of the cleared QUADROX-iR does not affect the performance specifications related to the intended use.

Based on the tests listed above, the modified device is safe and effective according to the intended use and is substantially equivalent to the originally cleared device.

Clinical Tests:

Clinical results are not required for this submission to support substantial equivalence.

Conclusion:

Based on the risk analysis, MAQUET Cardiopulmonary AG has conducted the appropriate design verification activities and believes that the modified device is substantially equivalent to the cleared MAQUET primary predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center -- WO66-G609
Silver Spring, MD 20993-0002

November 12, 2013

MAQUET Cardiopulmonary AG
Whitney Törning
Director of Regulatory
45 Barbour Pond Drive
Wayne, ND 07470

Re: K133265
Trade/Device Name: CARDIOHELP System with the QUADROX-iR Adult Oxygenator (Models 70100 and 70110 Bioline and Softline Coated) and the QUADROX-iR Small Adult Oxygenator (Models 50100 and 50110 Bioline and Softline Coated)
Regulation Number: 21 CFR 870.4360
Regulation Name: Non-roller type cardiopulmonary bypass blood pump
Regulatory Class: Class III
Product Code: KFM, DTZ, DTR, DTM
Dated: October 22, 2013
Received: October 23, 2013

Dear Ms. Törning:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133265

Device Name: CARDIOHELP System (including QUADROX-iR)

Indications for Use The CARDIOHELP System is a blood oxygenation and carbon dioxide removal system used to pump blood through the extracorporeal bypass circuit for circulatory and/or pulmonary support during procedures requiring cardiopulmonary bypass (for periods up to six hours). It is also intended to provide circulatory and/or pulmonary support during procedures not requiring cardiopulmonary bypass (for periods up to six hours).

The CARDIOHELP System in configuration with the HLS/HIT Set Advanced is intended to be used within the hospital environment and outside the hospital environment (for periods up to six hours), e.g. for intra- and inter-hospital transport.

The CARDIOHELP System in configuration with the QUADROX-iR is intended to be used in extracorporeal circulation during cardiopulmonary bypass in cardiac surgery (for periods for up to six hours).

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M A Hillebrenner